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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,155	11/25/2003	Theodore R. Sana	10030511-1	8586

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AGILENT TECHNOLOGIES , INC.
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EXAMINER	
KIM, YOUNG J	
ART UNIT	**PAPER NUMBER**
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,155	SANA ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 33-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The present Office Action is responsive to the Amendment received December 18, 2006.

Preliminary Remark

Claims 10-32 have been canceled.

Claims 33-38 are new.

Claims 1-9 and 33-38 are pending and under prosecution.

Claim Rejections - 35 USC § 112

The rejection of claims 1-9 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of synthesizing a plurality of biopolymers at a predetermined locations of a surface of a substrate, wherein one or more of said feature locations comprises degenerate biopolymers, wherein said biopolymers are nucleic acid (i.e., polynucleotide, oligonucleotide), does not reasonably provide enablement for the method wherein said degenerate biopolymers are polypeptides, made in the Office Action mailed on September 14, 2006 is withdrawn in view of the Amendment received on December 18, 2006, amending the claims to the scope which have been noted as being enabling.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects

for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1-7 and 9 under 35 U.S.C. 102(e) as being anticipated by Cronin et al. (U.S. Patent No. 6,027,880, issued February 22, 2000, filed October 10, 1995, priority October 26, 1993), made in the Office Action mailed on September 14, 2006 is maintained for the reasons already of record.

Applicants' arguments presented in the Amendment received on December 18, 2006 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments," section.

The Rejection:

Cronin et al. disclose a method of synthesizing a cystic fibrosis mutation chip which comprises a plurality of oligonucleotides immobilized at a predetermined locations, wherein said array comprises a reference sequence tiled thereto, followed by the tiling of the subgroups of oligonucleotides which comprises the same sequence as that of the reference oligonucleotide sequence excepting that said subgroups of oligonucleotides comprises at least one nucleotide that is different from the reference sequence (i.e., interrogation position) (Figures 1 and 5; column 2, lines 43-49; column 3, lines 36-40; column 11, lines 24-28, 33-35, and 42-46).

Cronin et al. disclose that the array is fabricated via photolithography, which comprises the steps of providing nucleotide monomers onto an array substrate, said monomers being blocked at their 5'-OH ends with photoremovable blocking group, followed by their deprotection via mask-mediated photolithography (thus activation). The processes are repeated subsequent to the deprotection steps, so as to fabricate the array (column 52, lines 13-28), thereby clearly anticipating claims 1-7.

With regard to claim 9, the photolithography is mediated via computerized process (column 54, lines 14-18).

Response to Arguments:

Applicants contend that the disclosure of Cronin et al. fails to disclose or suggest at least the following element of claim 1.

A – Cronin et al. do not disclose/suggest a substrate on the surface of which a plurality of biopolymers comprising nucleotides are synthesized at predetermined degenerate biopolymers comprising nucleotides:

- Applicants contend that this is clear from the discussion in the reference, for example, at column 3, lines 38-43, wherein the patentee states that each of the variant is assigned a designation and an array of pooled probes is provided with each pool occupying a separate cell of the array (page 8, 3rd column, Response)

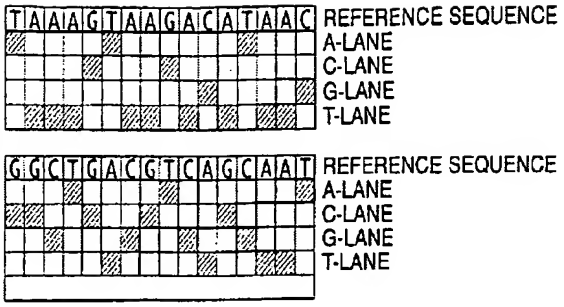
  This argument is not found persuasive.

  What is clear from Cronin et al. reference are the followings:

  Cronin et al. disclose a microarray comprising a substrate, wherein immobilized thereto, are polynucleotide probes (thus biopolymers), said polynucleotide probes comprising a first polynucleotide probe comprising a reference sequence, a second polynucleotide probe comprising all of the sequence of said first polynucleotide probe except for an interrogation position nucleotide, a second polynucleotide probe comprising all of the sequence of said first polynucleotide probe, except for an interrogation position nucleotide which is different from said second polynucleotide probe.

  This embodiment is clearly disclosed on column 2, lines 34-49 and Figure 5 of Cronin et al.'s disclosure (see below).

In a second embodiment, the invention provides a tilin; strategy employing an array comprising four probe sets. A first probe set comprises a plurality of probes, each prob comprising a segment of at least three nucleotides exactl; complementary to a subsequence of the reference sequence the segment including at least one interrogation positio complementary to a corresponding nucleotide in the refer ence sequence. Second, third and fourth probe sets eac comprise a corresponding probe for each probe in the firs probe set. The probes in the second, third and fourth prob sets are identical to a sequence comprising the correspond ing probe from the first probe set or a subsequence of at leas three nucleotides thereof that includes the at least on interrogation position, except that the at least one interro gation position is occupied by a different nucleotide in each of the four corresponding probes from the four probe sets.



In addition, according to Applicants' own definition found in the instant specification, a "degenerate biopolymer" is defined as below (from section [0032]):

> The phrase "degenerate biopolymers" refers to ***biopolymers that comprise one or more sites of degeneracy***, for example, less than 10, less than 5, less than 3, or less 2 such sites. A site of degeneracy generally comprises a contiguous stretch of ***1*** to 5 nucleotides in length, one to 4 nucleotides in length, one to 3 nucleotides in length, one to 2 nucleotides in length, ***one nucleotide in length***. The nucleotides of the **degenerate sites** are **degenerate nucleotides where the nucleotide(s) of a respective degenerate site differ from nucleotide(s) in corresponding positions of another biopolymer,** the biopolymers being otherwise generally of the same sequence composition. The nature and number of nucleotides in a degenerate site are generally determined by the nature of related sequences in a target sample whether the composition of such target sample is known or unknown.

As it is clearly seen on Figure 5, the polynucleotide probe sequence on, "A-LANE" comprises the same sequence as that of the reference polynucleotide probe sequence, except at the position of interrogation, wherein the, "T" nucleotides are replaced with an, "A" nucleotide.

Such polynucleotide probe sequence would clearly fall within the definition of the term, "degenerate biopolymer."

Hence, Applicants' arguments to this respect is not found persuasive.

B) Cronin et al. fails to disclose or suggest a method of synthesis wherein a mixture of biopolymer subunit precursors is employed at a feature site to form the feature location comprising the degenerate biopolymers.

- Applicants contend that Cronin et al. do not disclose such a feature, and as a matter of fact, Cronin et al. employ photolithography where masks are employed (page 8, bottom paragraph through page 9, 1st paragraph, Response)

Applicants are advised that for Applicants to argue a claim limitation, the claim limitation has to support Applicants' contention.

In the instant situation, the term, "mixture of biopolymer subunit precursors" is dependent on the previous limitation imposed by the phrase, "in each round of multiple rounds of subunit additions, providing **one** or more biopolymer subunit precursors at each of multiple feature location on said surface."

Clearly, the entire breadth and scope of the claims involve a method which employ a single biopolymer subunit precursor at each of the multiple feature location of the surface.

To this respect, the photolithographic method employed by Cronin et al. would clearly meet this limitation. As it is well known and established in the art, photolithographic method involves photoactivation of particular type locations (thus multiple feature location) via masking, followed by the application of a particular type of nucleotide for linkage.

Clearly, when one of ordinary skill in the art, reading the entire disclosure of Cronin et al., would recognize that a nucleotide being incorporated at particular location may be a wild type, or a "degenerate," based on whether said nucleotide is being incorporated at the wild type polynucleotide probe sequence, or a polynucleotide probe sequence comprising an interrogation nucleotide.

Applicants' arguments are not found persuasive, and thus the rejection is clearly maintained.

Applicants' arguments are not found persuasive for claim 1, and thus, the rejection of claims 2 and 3 are also maintained for the reasons already of record.

Applicants' arguments are not found persuasive for claims 4-7 and 9 as already fully discussed for the rejection of claim 1, and thus the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103 - Maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Cronin et al. (U.S. Patent No. 6,027,880, issued February 22, 2000, filed October 10, 1995, priority October 26, 1993) in view of Baldeschwieler et al. (WO 95/25116, published September 21, 1995), made in the Office Action mailed on September 14, 2006 is maintained for the reasons already of record.

Applicants' arguments presented in the Amendment received on December 18, 2006 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

The Rejection:

The teachings of Cronin et al. have already been discussed above.

Cronin et al. do not explicitly disclose that the method of synthesizing the array involve a dispenser comprising at least one droplet dispensing device.

Baldeschwieler et al. disclose a method of synthesizing an array via use of an inkjet technology, wherein the method involves the attachment of molecules onto a substrate surface (page 1, lines 23-25), for sequential synthesis of polynucleotides (page 2, lines 1-3), wherein the reagents are dispensed from a microdrop dispensing device (page 3, lines 14-15).

The artisans teach the deprotection step (i.e., activation of the protected monomers) so as to "grow" the nucleotides thereto (page 4, lines 1-20).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Cronin et al. with the teachings of Baldeschwieler et al., thereby arriving at the claimed invention for the following reasons.

The art of microarray is replete with different types of fabrication methods, such as photolithographic method (as employed by Cronin et al.), capillary deposition (developed by Pat Brown), inkjet deposition (as employed by Baldeswieler et al.), etc.

Hence, one of ordinary skill in the art at the time the invention was made would have been motivated to employ any of the well known methods of fabrication microarray, such as that of Baldeschwieler et al., for fabricating the array disclosed by Cronin et al.

In addition, it is also clearly known that the photolithographic method of fabricating a microarray is costly, as a plurality of mask must be employed for fabricating a single type of array. Hence, one of ordinary skill in the art at the time the invention was made would have been further motivated to find a more cost-efficient alternative technology, such as that of Baldeschwieler et al., thereby arriving at the claimed invention.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Response to Arguments:

Applicants' arguments rely on the rejection of claim 4, which have already been addressed along with the rejection of claim 1. As Applicants do not present any new arguments, the present rejection is maintained for the reasons already set forth above.

The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Hanks et al. (Methods in Enzymology, 1991, vol. 200, pages 525-532) in view of Baldeswieler et al. (WO 95/25116, published September 21, 1995), made in the Office Action mailed on September 14, 2006 is maintained for the reasons already of record.

In addition, claims 33-38 are included herein, as being necessitated by Amendment.

Applicants' arguments presented in the Amendment received on December 18, 2006 have been fully considered, but they are not found persuasive for the reason set forth in the, "Response to Arguments" section.

The Rejection:

Hanks et al. disclose a method of using degenerate oligonucleotides probes so as to identify clones that encode protein kinases (page 525, 3rd paragraph).

The artisans recite the importance in being able to identify proteins of known functions which have not yet been discovered (page 525, 1st paragraph; in the phrase, "[t]he identification and characterization of novel protein kinases should lead to new insights into how cells regulate their activities").

The artisans disclose a known method of identifying homologous nucleic acids via low-stringency hybridization condition (page 525, 2nd paragraph), and in this context, disclose a "new" way of identifying homologous sequences (page 525, 3rd paragraph).

The artisans explicitly disclose that degenerate oligonucleotide probes are employed in a hybridization assay, wherein said degenerate oligonucleotide probes are designed to

recognize target sequences that encode short stretches of six to nine highly conserved amino acid residues found within the catalytic domains (page 525, 3rd paragraph).

The artisans disclose that, "virtually all of the codon possibilities for a conserved stretch can be included in the probe mixture, thereby assuring that many different protein kinase genes (cDNAs) will be recognized." (page 525, 3rd paragraph).

Hanks et al., however, employ the degenerate oligonucleotides in an in-solution assay via radioactive labeling (page 529).

Baldeschwieler et al. disclose a method of synthesizing an array via use of an inkjet technology, wherein the method involves the attachment of molecules onto a substrate surface (page 1, lines 23-25), for sequential synthesis of polynucleotides (page 2, lines 1-3), wherein the reagents are dispensed from a microdrop dispensing device (page 3, lines 14-15).

Baldeschwieler et al. disclose the step-by-step addition of protected monomers, followed by the washing of uncoupled monomers, followed by the deprotection step (or activation), followed by the repeat of the addition of second protect monomers (page 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hanks et al. with the teachings of Baldeswiechler et al., thereby arriving at the invention as claimed for the following reasons.

The art of microarray technology has been well-established, wherein its advantage of allowing simultaneous detection of a plurality of (thousands) of target analytes is widely known and accepted.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to fabricate a microarray comprising a plurality of degenerate oligonucleotide probes (of Hanks et al.), for the well known benefit of simultaneously identifying a plurality of homologous genes of interest.

Given the fact that Hanks et al. gave all the necessary guidance for generating degenerate oligonucleotide probes for identifying related genes; whereby coupled with the teachings of Baldeswiechler et al. who gave all the necessary guidance for fabricating an array via use of a dispenser, one of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success at combining the teachings so as to arrive at the method of fabricating on a solid substrate, a plurality of degenerate oligonucleotide probes.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Response to Arguments:

Applicants state that Hank is completely devoid of any teaching relevant to the presently claimed invention (page 11, 3rd paragraph, Response).

Applicants state that, for example, Hanks fails to disclose or suggest a method for synthesizing a plurality of biopolymers comprising nucleotides at predetermined feature locations on a surface of a substrate wherein one or more of said feature locations comprises degenerate biopolymers comprising nucleotides.

Applicants contend that Hanks refers only to putting cDNA libraries for novel protein kinases onto filter materials, but does not disclose or suggest using multiple rounds of subunit additions in which one or more biopolymer subunit precursors comprising nucleotides are placed at each of multiple feature locations on the surface to form the plurality biopolymers on the surface (page 11, 3rd paragraph, Response).

Applicants state that while the Office action appears to recognize these deficiencies, the Office action asserts that the teaching of Baldeschwieler combined with that of Hanks cures all of the deficiencies of Hanks and that one "skilled" in the art would be motivated to

combine the teachings of the references to arrive at the presently claimed invention for the well known benefit of simultaneously identifying a plurality of homologous genes of interest.

Applicants' contention is that one of ordinary skill in the art would not have come to this motivation absent Applicants' own disclosure (page 11, bottom paragraph though page 12, 1st paragraph, Response).

This argument is not found persuasive for the following reasons.

Applicants appear to be severely undermining the skill level of the ordinarily skilled artisan in question.

It is a fact that microarrays have been well established in the art, for the well known benefit of analyzing a plurality of target nucleic acid sequences simultaneously.

If Applicants would dispute such knowledge, the Office would be glad to fax the Applicants the disclosure by Lockhart et al., published on 1997.

It is another fact that methods of fabrication, such as photolithography, or ink jet deposition, had also been well established in the art (as evidenced by the date of Baldeschwieler).

What Applicants are contending is that even at the fact that the benefit of microarrays had been well established, along with various types of their fabrication methods, one of ordinary skill in the art would not have been motivated to combine the teachings of Hanks with the teachings of Baldeschwieler, for the well established benefit of simultaneously screening for thousands of target nucleic acids.

This contention is, simply not persuasive.

What is clear is that Hanks disclose a method of using ***degenerate oligonucleotide probes*** so as to identify clones that encode protein kinases.

What is clear is that Hanks already recognizes the importance of identifying proteins of known functions which ***have not yet been discovered***.

"The identification and characterization of novel protein kinases should lead to new insights into how cells regulate their activities"

What is clear is that Hanks disclose that their method identifies homologous sequences.

What is clear is that Hanks ***explicitly disclose that degenerate oligonucleotide probes are employed in a hybridization assay***, wherein said degenerate oligonucleotide probes are designed to recognize target sequences that encode short stretches of six to nine highly conserved amino acid residues found within the catalytic domains (page 525, 3rd paragraph).

What is clear is that Hanks do not employ a microarray format.

However, one of ordinary skill in the art at the time the invention was made would have been clearly motivated to employ the microarray technique, for the advantage of simultaneously screening for thousands of related sequences.

Hanks already employs probe to target hybridization assay, wherein the art of microarray is known to improve upon, that is, increasing the information content.

Hence, one of ordinary skill in the art, at the time the invention was made, would not only have been motivated, but also would have had a clear expectation of success at combining the teachings of Hanks with the teachings of Baldeschwieler et al., as probe to target hybridization detection on microarrays have already been conducted and disclosed by plenty of art, prior to Applicants' time of filing.

Therefore, the invention as claimed is *prima facie* over the cited references, and the rejection is maintained.

With regard to Applicants' contention of providing a "mixture" of biopolymer subunit precursors, Applicants are advised that the term is limited to the previous claim limitation stating the phrase, "providing one or more biopolymer subunit precursors at each multiple feature locations."

As already articulated above, an embodiment drawn to one biopolymer subunit precursor would allow the mixture to have a single type of biopolymer subunit at the feature location. Applicants' definition of the term, "mixture" does not exclude a plurality of same nucleotides, and certainly, instant claims encompass such an embodiment.

Conclusion

No claims are allowed.

Applicants are advised that amending claim 33 to incorporate the invention defined in section [0091], in particular:

> "The predetermined ratio of the biopolymer subunit precursors is adjusted based upon what is known in the scientific literature about the expected target sequences to be detected and by the expected complexity of the degenerate biopolymers in the sample solution, and so forth."

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee

pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Primary Examiner
Art Unit 1637
3/4/2007

YOUNG J. KIM
PRIMARY EXAMINER

YJK